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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,801	10/16/2003	Shibnath Ghosal	4822-129 US	7933

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EXAMINER	
WEBB, WALTER E	

ART UNIT	PAPER NUMBER
1612	

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08/03/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/686,801	GHOSAL, SHIBNATH	
	Examiner	Art Unit	
	WALTER E. WEBB	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7,9,13,22,24-30,34 and 35* is/are pending in the application.

4a) Of the above claim(s) *28,29 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7,9,13,22,24-27,30 and 34* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/19/2010 has been entered.

Applicants' arguments, filed 7/19/2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Objections

Claim 1 is objected to because of the following informalities: The abbreviation for chromium is –Cr-- not “CR” as recited in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103--previous

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1) Claims 1, 2, 7, 9, 13, 22, 24-27, 30 and 34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Janjua (Hamdard Medicus 1991) in view of Ghosal (US 6,124,268) and Riley et al. (EP 0037144 published October 7, 1981).

Janjua teaches that administration of organic chromium and some herbs were found to be of benefit and advisable during diabetes. One of the herbs identified as being advisable during diabetes was *Phyllanthus emblica* (Amla fruit a.k.a. *Emblica officinalis*), which was shown to contain about 2.5µg/g of chromium (see table at pg. 105). Janjua also teaches using chromium supplementation for improving glucose tolerence in animals suffering from insulin disorder (see first and second paragraphs at pg. 104). Janjua also prefers organic chromium salts for treating diabetes due to their being more acceptable to the body (see pg. 105, second parapraph).

As a plant species of the instant claims (claims 10 and 11), *Phyllanthus emblica,* which naturally contains chromium, would inherently comprise an antioxidant-chromium complex. It would also inherently comprise a low molecular weight hydrolyzable tannin having a molecular weight below 2000 or 1000, as per **claims 9 and 27**.

The reference differs from the instant claims insofar as it does not teach a purified tannin fraction of the plant species or a chromium content of 0.01 to 20% of the complex.

Ghosal teaches a purified tannin fraction of *Phyllanthus emblica* for use in pharmaceutical and nutritional compositions (see Abstract and Example 1 at col. 6). The composition is taught to be an enriched natural anti-oxidative blend, which has

advantageous antioxidant and free radical captodative properties (see col. 1, lines 9-16). Hydrolysable tannins Emlicanin-A and –B were identified as the bioactive compounds (see col. 4, lines 40-42). Ghosal does not teach an antioxidant-chromium complex.

Riley et al. teaches stable chromium complexes for dietary supplementation for humans and lower animals, which are useful for treating diabetes (see Abstract). The reference teaches adding pharmaceutical excipients and carriers like sugars and oils (see pg. 9, lines 24-36). The reference teaches that the dosage of chromium complex will vary with the particular condition being treated (see pg. 8, lines 11-14). For example, single dosage amounts range from 0.15 to 100 micrograms of chromium per kg of body weight (see pg. 8, lines 14-19). The reference also teaches multivitamin/mineral compositions comprising vitamin A and C (**claims 24 and 25**).

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to combine chromium with the purified hydrolysable tannins of the *Phyllanthus emblica* fruit, since Janjua teaches combining chromium with *Phyllanthus emblica* fruit for treating diabetes, and Ghosal identified the purified tannin fraction as the medically relevant components of the fruit, specifically recognizing the hydrolysable tannins as the bioactive compounds.

In regard to the percentage of chromium in the complex, it would have been obvious to determine result effective amounts of the chromium beneficially taught by the cited references, especially within the broad ranges instantly claimed. This is deemed merely a matter of judicious selection and routine optimization which is well within the

purview of the skilled artisan. For instance, Ghosal teaches a tablet formulation comprising 96mg of CAPROS, which has 27% Emblicanin-A and 23% Emblicanin-B (48 mg total), while Riley teaches a dosage range for chromium of 0.15 to 100 micrograms per kilogram of body weight. A person weighing 200lbs or 91kg would have been administered about 9.1mg of chromium based on 100 micrograms per kg of body weight, which comes to about 19% of the amount of Emblicanin-A + -B.

The limitation "wherein the chromium is prevented from getting converted from CR(III) which is therapeutic, to Cr(VI), which is toxic", has been interpreted as a limitation for use of a specific type of chromium, i.e. chromium III, which is taught in Janjua and Riley et al. Furthermore, the conversion of chromium III to chromium IV requires oxidation which would be expected to be inhibited if it is administered with an antioxidant. Both Janjua and Riley et al. teach administering chromium III with an antioxidant.

New

2) Claims 1, 2, 7, 9, 13, 22, 24-27, 30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Riley et al. (supra) in view of Ghosal (supra) and further in view of Gilles et al., (US 6,248,375).

Riley et al., in addition to that taught above, teaches a specific multivitamin/mineral composition comprising chromium (III) and Ascorbic Acid (Vitamin C).

Riley et al. differs from the instant claims insofar as it does not teach adding a purified hydrolysable tannin fraction from Phyllanthus emblica.

Ghosal, in addition to that taught above, teaches that the antioxidant composition from the Emblica officinalis fruit has much better anti-oxidative properties against reactive oxygen species and can stabilize and prolong the anti-oxidative properties of ascorbic acid (see col. 2, lines 4-8).

Gilles et al. teaches solid matrix nutritionals designed for persons with diabetes (see Abstract), where the nutritionals comprise vitamins and minerals such as ascorbic acid and chromium (see col. 14, lines 27-33). The reference teaches the importance of providing chromium and ascorbic acid further adding "that higher dietary requirements may exist for certain micronutrients such as ascorbic acid due to higher turnover in people with type 2 diabetes" (col. 10, lines 52-67).

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to add the purified hydrolizable tannin fraction of Ghosal to the chromium composition of Riley et al. since the composition of Riley et al. comprises ascorbic acid, and the composition of Ghosal would have stabilized and prolonged the anti-oxidative properties of ascorbic acid, which was known to be of importance in persons with type 2 diabetes due to the higher turnover of this micronutrient, as taught by Gilles et al.

In regard to the percentage of chromium in the complex, it would have been obvious to determine result effective amounts of the chromium beneficially taught by the cited references, especially within the broad ranges instantly claimed. This is deemed

merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. For instance, Ghosal teaches a tablet formulation comprising 96mg of CAPROS, which has 27% Emblicanin-A and 23% Emblicanin-B (48 mg total), while Riley teaches a dosage range for chromium of 0.15 to 100 micrograms per kilogram of body weight. A person weighing 200lbs or 91kg would have been administered about 9.1mg of chromium based on 100 micrograms per kg of body weight, which comes to about 19% of the amount of Emblicanin-A + -B.

The limitation "wherein the chromium is prevented from getting converted from CR(III) which is therapeutic, to Cr(VI), which is toxic", has been interpreted as a limitation for use of a specific type of chromium, i.e. chromium III, which is taught in Riley et al. Furthermore, the conversion of chromium III to chromium IV requires oxidation which would be expected to be inhibited if it is administered with an antioxidant. Riley et al. teaches administering chromium III with an antioxidant.

Response to Arguments

Applicant has pointed out the deficiencies in each of the cited references. However, the rejection is based on the combination of references. The test of obviousness is not the express suggestion of the claimed invention in any or all of the references, but what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them. The artisan would have understood that combining the antioxidant composition of Ghosal with chromium (III) of Riley et al. would have been useful for treating diabetes following the suggestion of

Janjua that administration of organic chromium and *Phyllanthus emblica* fruit were found to be of benefit and advisable in treating diabetes.

Applicant further argues that the present invention provides unexpected results in the form of showing substantially improved effect when an external source of chromium is mixed with a *Phyllanthus emblica* antioxidant fraction. Applicant's show, in a diabetic mouse model, improved blood sugar lowering effect of the phylanthus emblica extract plus chromium as opposed to phylanthus emblica extract alone. However, since Janjua teaches administering phyllanthus emblica (Emblica officianalis) in combination with an external source of organic chromium to treat diabetes, applicant's results are not unexpected. The artisan would reasonably expect the addition of chromium to improve blood glucose levels, since chromium is known as "an essential micronutrient for the maintenance of normal glucose tolerance in animals", as taught by Riley et al. (see pg. 1, lines 5-7).

Even if applicant's data supported an unexpected result, the instant claims are not commensurate in scope with these results. For example, Table 2 at page 30 of the specification shows use of Phyllanthus emblica extract at 10mg/kg plus Cr^{3+} at 40µg/kg, while the claims recite "wherein the chromium content of the complex is from 0.01 to 20% of the complex". Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed

to see if the results occur over the entire claimed range. Here, it is not clear whether the results occur over the entire range "0.01 to 20%" for the amount of chromium.

Established precedent holds, to establish unexpected results over a claimed range, applicants should compare a sufficient number of tests both inside and outside the claimed range to show the criticality of the claimed range. *In re Hill*, 284 F.2d 955, 128 USPQ 197 (CCPA 1960).

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb
/Walter E Webb/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612